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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/228,926	04/18/1994	ENZO PAOLETTI	4543102430	4171

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/228,926	PAOLETTI ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-40,52 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,34,52 and 53* is/are rejected.

7)☒ Claim(s) *35-40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: 3 attachments: Copy of date-stamped cover for PNAS 79(23); copy of 06/445892; copy of 06/445451.

DETAILED ACTION

After a considerable hiatus, prosecution is resumed in this application. To review the prosecution history, this application was filed on 4/18/1994. Because of its filing date, if issued it is "grandfathered" with a 17-years-from-issue term not a 20-years-from-filing term. This application was filed as a file wrapper continuation of 07/881995, which was filed on 5/4/1992. Benefit is claimed to a series of continuations dating back to 6/19/1984, and beyond that to continuations-in-part dating back to 12/24/1981.

In 1996, all claims were indicated as allowable, and the application was sent to interference. Eventually, the Board decided that there was no interference-in-fact. Applicants subsequently cancelled the claims which had been subjected to double patenting rejections, withdrew the terminal disclaimers which had been filed to overcome those rejections, and added new claims 52 and 53. Claims 33-40, 52 and 53 remain pending.

There have been significant changes in case law since the claims were indicated as allowable in 1996. Notably, the decision in *University of California v. Eli Lilly and Co.* (43 USPQ2d 1398, U.S. Court of Appeals Federal Circuit No. 96-1175, Decided July 22, 1997, 119 F3d 1559) raised the standard for satisfaction of the written description requirement. Guidelines were published for treatment of generic claims.

Claims 33-40 involve a donor DNA flanked by vaccinia virus DNA from a nonessential region, whereby the donor DNA is expressed under vaccinia control when the DNA is incorporated into the virus by in vivo recombination. In other

words, the flanking DNA comprises a vaccinia promoter, and the donor DNA is oriented so that it is operatively linked to the promoter. Claims 33 and 34 are fully generic with regard to the vaccinia flanking DNA and expression control element.

Claim 52 is even more broadly drawn, to donor DNA comprising isolated DNA not naturally occurring in vaccinia virus flanked by vaccinia nonessential region DNA. Claim 53 broadens the scope still further, expanding from vaccinia to any poxvirus.

In 1994, when this application was filed, there was considerable knowledge in the art for poxvirus nonessential regions, and for vaccinia promoters, so there is no reason to reject the claims based upon inadequate description or enablement. However, it must be considered whether or not these claims are adequately described and enabled in all of the prior applications, and whether prior art is available to be applied if benefit is denied.

Priority - Poxvirus nonessential region

In regard to poxvirus nonessential regions, the instant specification teaches that the central regions of poxvirus genomes are relatively conserved, and teaches vaccinia nonessential regions in the region differing between L and S variants of WR, the HindIII F fragment, and the Ava I H fragment. The specification teaches nothing about nonessential regions in other poxviruses.

In Falkner v. Inglis (79 USPQ2d 1001), the Federal Circuit ruled that brief mention of vaccinia virus was sufficient to describe generic nonessential regions of poxvirus, in light of the state of the art in 1990. Therefore, analysis focuses on the state of the art between 8/27/1987 and 6/14/1990.

For poxviruses other than vaccinia, Moyer et al (Virology 102:119-132, 1980) taught deletions in rabbit poxvirus, which is an orthopoxvirus. Esposito et al (Virology 165:313-6, July 1988) taught nonessential regions and insertion of foreign DNA for raccoonpox, another orthopox virus. For fowlpox, Boyle et al (Virus Research 10:343-356, 1988) and Taylor et al (Vaccine 6:497-503 and 6:504-508, both December 1988) taught nonessential regions and insertion of foreign DNA. Therefore, those skilled in the art after 1988 had routine knowledge of nonessential regions for multiple species of vertebrate poxviruses and routine knowledge of how to insert foreign DNAS into the genome of multiple species of vertebrate poxviruses, and by 1994 those skilled in the art had routine knowledge for the full gamut of poxviruses. Therefore, the effective date for generic poxvirus nonessential regions is seen as June 14, 1990.

Priority - Expression under vaccinia control

Despite being written before the *Lilly* decision, the reasons for allowable subject matter in the action mailed 4/22/96 contains an analysis of the disclosure supporting generic claims involving “expression under vaccinia control”, such as claims 33-40. The analysis concluded that the earliest filed parent application 06/334,456 (filed 12/24/1981) discloses one species which is within the scope of the broadly claimed subject matter. Application 06/446,824 (12/8/1982) provided additional disclosure, including two species of expression under vaccinia control, and the representative examples were therefore seen as providing adequate support at least on December 8, 1982 for a generic claim of "expression under vaccinia control". This was sufficient to antedate the publication by Mackett et al (Proceedings of the National Academy of Sciences USA 79 (23):7415-7419, 1982),

because this document was not available to the public until 12/14/1982, see stamped journal cover as evidence of receipt date. However, since 1996, the disclosure in other patent applications has become available under 35 USC 102(e).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Moss et al US 6998252. In making this rejection, applicants are denied the benefit of application 06/334,456 (filed 12/24/1981) because the single disclosed species is not seen as providing an adequate written description of the generic invention claimed. In priority application 06/445451 (11/30/1982), Moss discloses a plasmid pMM20, which has a herpes simplex TK gene under vaccinia expression control and flanked by vaccinia DNA from a nonessential region, see pages 28-30. Therefore Moss meets each and every limitation of these claims. This rejection is not applied to claims 35-40, because Moss does not teach or suggest the nonessential regions or the particular constructs recited in these claims.

For applicant's convenience, copies of the original abstract, specification, and claims are provided for Moss priority applications 06/445451 and 06/445892.

Claim 52 is rejected under 35 U.S.C. 102(b) as being anticipated by Boyle et al (Virus Research 10:343-356, 1988) or Taylor et al (Vaccine 6:504-508, December 1988). In making this rejection, applicants are denied the benefit of application 07/090,209 and earlier applications, because the disclosed species of vaccinia nonessential regions are not seen as providing an adequate written description of the generic invention claimed. Boyle et al teaches donor DNA comprising foreign genes flanked by DNA sequences homologous to a nonessential region of fowlpox virus, see for example Figure 2. Taylor et al also teaches donor DNA comprising foreign genes flanked by DNA sequences homologous to a nonessential region of fowlpox virus, see the passage spanning pages 497-498. Therefore the references meet the limitations of these claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Note, only patented claims to plasmids and DNAs are cited in the following double patenting rejections, because restriction was required between this subject matter and viruses per se and methods of using DNAs to make modified viruses in the direct ancestry of this application.

Claims 33, 52 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5747324. (Panicali is common inventor.) Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims encompass the previously patented plasmids. Please note, the patent was filed earlier that the current application, so only a one-way obviousness analysis is required.

Claims 33, 52 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5614404. (Panicali is common inventor.) Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims encompass the previously patented plasmids. Please note, the patent was filed earlier that the current application, so only a one-way obviousness analysis is required.

Claim 52 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5093258. (Panicali is common inventor.) Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claim encompasses the previously patented DNAs. Please note, the patent was filed earlier that the current application, so only a one-way obviousness analysis is required.

Claims 52 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6632438. (Paoletti is common inventor.) Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented subject matter. Please note, although this application has an earlier filing date, the subject matter of claims 52 and 53 was presented for the first time on 11/21/2005. Therefore a one-way analysis of obviousness is appropriate.

Claims 52 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4 and 6 of U.S. Patent No. 6699475. (Panicali is common inventor.) Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 52 encompasses the previously patented subject matter; claim 53 encompasses the vaccinia species of the patented subject matter, which is an obvious species in view of the disclosure supporting the patent claims. Please note, although this application has an earlier filing date, the subject matter of claims 52 and 53 was

presented for the first time on 11/21/2005. Therefore a one-way analysis of obviousness is appropriate.

Allowable Subject Matter

Claims 35-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

The information disclosure statement filed 11/14/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not include the inventor and publication date for each U.S. patent as required by 37 CFR 1.98(b)(1), or the publication date for each foreign patent as required by 37 CRF 1.98(b)(5), or the title of each publication as required by 37 CFR 1.98(b)(5). Also, among the documents listed, copies of the declarations bys Dr. Stunnenberg, Moyer, Condit, Wittek, Drillien, and Hruby could not be found, and none of the foreign patents except EP 0353851 could be found, in the IFW file.

The IDS has been placed in the application file, but the line-out information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

5/15/08